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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

LANDREM, KAMRIN R

ART UNIT PAPER NUMBER

3738

DATE MAILED: 04/23/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/753,448

Applicant(s)

SHELSON, SUSAN I.

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-43 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-30, and 32-35 is/are rejected.
- 7) ☒ Claim(s) 5, 6 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The finality of the last Office action has been withdrawn in view of the Request for Reconsideration, Paper No. 7. Claim 44 has been rejoined with the pending claims for examination purposes.

In response to applicant's request for clarification concerning claims 26-43, it appears that Paper No. 6 contains a typographical error. The examiner inadvertently typed 26 instead of 36 in Paper No. 6. Claims 36-43 are allowed and claims 26-35 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,7-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al (USPN 5,743,874).

The claims as amended still broadly read on Fischell et al.

Claim 1, with respect to a delivery system comprising, a catheter (10), an inflatable device (50), a slidable outer tube (20), a self-expanding stent (60), radiopaque marker bands (152,180,182), a fluid port (33), a tapered distal tip (21), a fluid lumen (34), guidewire lumen (43), and stent containment cavity (70), see Figs. 1-4 of Fischell et al. With regards to marker bands, Fischell does disclose, "one, two, or more radiopaque markers could be used with any integrated design", col. 5, line 28+.

Claim 17, with respect to method for implantation of a self-expanding stent, Fischell et al discloses (col. 3, lines 32-60) methods of use for delivery system comprising of delivering the device, implanting stent, inflating balloon, use of guidewire, providing axial movement between tubular member and outer member, retracting device, inflating balloon, deflating balloon, and withdrawing delivery system from patient. With regards to balloon's position relative to the stent, Fischell et al does disclose an inflatable device provided on the catheter and positioned at least below the distal portion of the self-expanding stent, see col. 3, lines 52+.

Claim 29, with respect to self-expanding stent and delivery system comprising a self-expanding stent (60), catheter (10) having distal end and configured to retain stent, and an inflatable device (50) overlapping with at least a portion of the stent (60) see Figs. 1-4 of Fischell and col. 3, lines 52+.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell in view of Helgersen et al (USPN 5,695,499).

Fischell et al discloses a delivery system comprising a self-expanding stent (60), a catheter (10) having a distal end, and an inflatable device (50) provided on the catheter and positioned either between the stent and the distal end or beneath a portion of the self-

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expanding stent. Fischell discloses all of the claimed elements except for the particulars pertaining to the method of reconstraining the stent (60) for effective positioning.

Helgerson et al teaches a method for reconstraining a stent using a delivery device that allows for the stent to be reconstrained and repositioned after partial deployment.

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the reconstraining method of Helgerson et al in order to effectively position the self-expanding stent of Fischell.

Claim 44, with regards to a self-expanding stent (60), a catheter (10) having a distal end, and an inflatable device (50) provided on the catheter and positioned either between the stent and the distal end or beneath a portion of the self-expanding stent, see Figs. 1-4 of Fischell. With regards to delivering the device, implanting the stent and inflating the expandable device, see col. 3, lines 20-63 of Fischell. With regards to method of releasing a portion of the self-expanding stent corresponding with a marker band on the catheter and reconstraining the stent, see col. 5, lines 29-65 of Helgerson.

Response to Arguments

Applicant's arguments with respect to claims 1, 17, and 29 have been considered but are moot in view of the new ground(s) of rejection.

In response to Paper No. 7, the examiner finds the applicant's arguments with respect to claim 1 unpersuasive. Applicant argues that third marker band is between the proximal and distal markers. Examiner directs applicant's attention to Fig. 4, 152 (proximal), 180 (distal), and 182 (between proximal and distal). As broadly claimed the applicant's claim does not recite that all marker bands are disposed on the same tubular

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member and therefore applicant's argument is unable to overcome the 35 U.S.C. 102(b) rejections.

The examiner finds the applicant's arguments with respect to claim 17 unpersuasive. Applicant argues that the inflation device of Fischell is not positioned beneath at least a portion of the self-expanding stent. Applicant doesn't recite that the balloon is positioned beneath at least a portion of the stent prior to deployment therefore the following recitation by Fischell overcomes applicant's argument; "the catheter is then pulled back until the deflated balloon lies within the expanded stent" (col. 3, lines 53-54). As broadly claimed the applicant's argument is unable to overcome the 35 U.S.C. 102(b) rejections.

The examiner finds the applicant's arguments with respect to claim 29 unpersuasive. With regards to applicant's arguments, see examiners response to claim 17.

Allowable Subject Matter

Claims 36-43 are allowed.

Claims 5,6, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

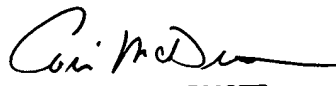
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-3905 for regular communications and 703-308-3905 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kamrin Landrem
Examiner
AU 3738

KRL
April 14, 2003


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700